



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/955,933	09/20/2001	Luba Cohen	2786-0191P	9933

7590 09/08/2004
BIRCH, STEWART, KOLASCH & BIRCH, LLP
P.O. Box 747
Falls Church, VA 22040-0747

EXAMINER

WARE, DEBORAH K

ART UNIT PAPER NUMBER

1651

DATE MAILED: 09/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/955,933

Applicant(s)

COHEN, LUBA

Examiner

Deborah K. Ware

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1-22 are presented for reconsideration on the merits.

Papers

The response with amendments filed February 4, 2004, has been received and entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 7, 10-11, 13, 16-17, 19, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by newly cited Fuhrman, note the previously enclosed PTO-1449 Form.

Claims are drawn to methods of lowering a risk factor in a patient, lowering at least two risk factors simultaneously and preventing a patient from suffering from a condition.

Fuhrman et al (hereinafter referred to as Fuhrman) teach administering to a patient an effective amount of a licorice extract which is water soluble, note abstract and page 269 lines 1-30. The effect of administering the extract prevents oxidative damage by free radicals which have been the cause of diverse diseases including cancer and

cardiovascular disease, note page 267, introduction, lines 1-3. The extract is glycyrrhizinic acid free, note page 268, Materials, lines 1-2.

Claims appear to be identical to Fuhrman and are therefore considered to be anticipated by the teachings of therein. Lowering the risk factors in a patient are inherent to the disclosure of Fuhrman because by reducing the potential of oxidative damage by free radicals a patient is at a lower risk of getting a disease such as blood pressure or blood glucose concentration. Also since the patient may not even suffer from the risk factor then by administering an identical licorice extract as claimed and disclosed by Fuhrman the lowering of a patient's risk factor is inherent to the teachings of the cited reference.

Claim Rejections - 35 USC § 103

Claims 6, 8, 12, 14, 18, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fuhrman, cited above.

Claims drawn to a method for treating inflammation by identifying a patient suffering with it and administering an effective amount of a licorice extract. Also method of treating a patient suffering from high blood triglycerides and high LDL levels without decreasing HDL level by administering the licorice extract is claimed.

Fuhrman is discussed above. Furthermore, Fuhrman discloses that patients have been identified to suffer from inflammation and high triglycerides and high LDL levels. Note page 268, lines 1-60 and note the abstract. The extract is made using ethanol or is an ethanol extract; see page 269 and page 270, figure 1.

The claims differ from Fuhrman in that a treatment of inflammation and LDL levels is not disclosed, per se.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to select the licorice extract of Fuhrman and to provide for treatment methods of inflammation and LDL levels. Fuhrman clearly teaches that their licorice extract eliminates free radical oxidation which causes inflammation and cardiovascular disease of which high blood pressure is related thereto. Also they teach that patients suffer from inflammation and heart disease as well as high LDL levels and their results have shown that their extract which is free of glycyrrhizic acid has been shown to reduce oxidative damage by free radicals. Thus, one of skill in the art would have expected successful results by employing the extract in treatment methods of such diseases. To modify Fuhrman for which to set forth a method of treatment by carrying out identifying a patient suffering from the disease such as high LDL levels or inflammation and administering thereto an effective amount of their extract is obvious to one of skill in the art especially since Fuhrman teach that the extract reduced free radical oxidation well known to cause inflammation and heart disease also related to high LDL levels. The claims are prima facie obvious.

Claims 9, 15, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fuhrman in view of admitted prior art (see specification at page 1, lines 10-12).

Claims drawn to a method for treating a patient suffering from a condition such as hypertension.

Fuhrman is discussed above.

Art Unit: 1651

Admitted prior art teaches that traditional extracts and in particular glycyrrhizinic acid are known to cause hypertension.

The claims differ from Fuhrman in that a treatment method for treating a condition is not specifically disclosed.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to administer the extract as disclosed by Fuhrman in a method for treating hypertension since the admitted prior art clearly teaches that traditional extracts containing glycyrrhizic acid are not used for treating hypertension. Thus, one of ordinary skill in the art would have expected successful results by administering the extract of Fuhrman for treating hypertension because their extract is glycyrrhizic acid free. Therefore, since the effects of administering an extract which contains the acid is known it would have been an obvious modification of the cited prior art to administer an extract which does not contain the acid and expect successful results for treating hypertension. The claims are prima facie obvious.

All claims fail to be patentably distinguishable over the state of the art discussed above and cited on the enclosed PTO-892 and/or PTO-1449. Therefore, the claims are properly rejected.

The remaining references listed on the enclosed PTO-892 and/or PTO-1449 are cited to further show the state of the art.

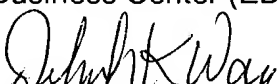
No claims are allowed.

Art Unit: 1651

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 571-272-0924. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


DEBORAH K. WARE
PATENT EXAMINER

Deborah K. Ware
August 27, 2004